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The following issues are outstanding in the pending application:

• Claims 9-10 are rejected under 35 USC 112; and

• Claims 1-10 are rejected under 35 USC 103.

Claim amendments

Claim 1 has been amended to more clearly define the subject matter of the subject invention. Claim 1 now recites a method for determining the optimum macronutrient content of a diet for an individual companion animal, comprising the steps of 1) providing over an extended and preselected period of time different food compositions to said animal in which each composition provides an enriched source of fat, protein or carbohydrate, such that said animal can select and consume different and preferred quantities of each said food compositions in order to achieve an optimum consumption of fat, protein and carbohydrate for said animal; 2) allowing said animal to consume the different and preferred quantities of fat, protein and carbohydrate from each of said compositions over the extended preselected period of time; and 3) determining, from the consumed amount of fat, protein and carbohydrate from each said compositions, a customized dietary regime that provides the optimum macronutrient content of a diet for said individual animal. Claim 4 has been amended to conform the subject matter to the amendment of claim 1. Claims 9 and 10 have been cancelled. No new matter has been added.

35 USC 112

Claims 9-10 are rejected under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Claims 9 and 10 have been cancelled, thus rendering this rejection moot.

35 USC 103

Claims 1-10 are rejected under 35 USC 103(a) as having subject matter unpatentable over U.S. Pub. No. 2001/0048955 to Forman et al. taken with U.S. Pat. No. 6,410,063 to Jewell et al., WO 10/97605 and WO 01/97630 in view of Rice ("The Dog Handbook", pages

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48-49), Romsos et al. (JAVMA vol. 182(1), pp 41-43 1983) and further in view of Serpell ("The Domestic Dog", pages 104-106, 1995) and Wills, Josephine ("Adult Maintenance", BSAVA Manual of Companion Animal Nutrition & Feeding, Chap. 3, pages 44-46, 1996). Applicant respectfully traverses this rejection.

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Foreman teaches a method for feeding a pet a balanced meal or supplement in which the meal includes a main course 24 having a high protein and fat content, a side dish 26 having a high carbohydrate content and a dog treat 28 preferably in the traditional shape of a bone or biscuit which the dog has been preconditioned to perceive as a reward. The meal is provided in a tray with a removable cover and is divided into separate compartments in which the main course, side dish and treat are placed. The food items placed in the tray for the main course 24, treat 28 and side dish 26 are selected by the assembler of the tray based on the criteria listed in the Foreman specification (Para [0043]) for the main course, side dish and treat. The meal is suppose to provide greater satisfaction and enjoyment for the animal than prior art dog food.

Jewell discloses a method for inducing a state of ketosis in a canine by means of dietary manipulation. The method comprises feeding to a canine in need of such ketosis, on a regular basis, a diet of a single pet food that includes carbohydrate measured as nitrogen free extract of about 0 to about 20 wt. %, protein of about 25 to about 70 wt. %, and fat of about 20 wt. % to about 70 wt. %. The diet is essentially a high fat, low carbohydrate diet that results in the attainment of a ketonic state (Col. 5, lines 12-13).

WO 01/97605 is directed to a food pack that includes at least two vessels, each containing a pet food product, in which an animal is fed one pet food product for the morning meal and the second pet food product is fed for the afternoon/evening meal (Page 3, lines 24-27; page 4, line 1). One of the pet food products has a higher content of fat than the other pet food product. Thus, the morning meal has a fat content between 20-70% and the afternoon/evening meal has a fat content of between 25-75% in which the afternoon/evening meal should be higher in fat content than the morning meal by at least 5%. WO 01/97630 is directed to a dietary regime for companion animals in which one pet food is fed as the morning meal and a second pet food product is fed as the afternoon/evening meal. The

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morning meal has a higher protein content that the afternoon/evening meal and the afternoon/evening meal has a higher fat content that the morning meal.

Rice describes free-choice feeding as "leaving a least a one-day supply of premium dry dog food where it is accessible to Daisy at all times." Further, " - - - she should be fed free-choice premium dry puppy food, plus two small daily meals of canned and dry food mixed." Serpell is directed to the evolution, behavior and interactions of dogs. Regarding palatability, Serpell states that dogs prefer meat to vegetable protein and display preferences for one meat over the other. Further, they prefer canned or semi-most food to dry food and cooked to raw meat, and canned meat to the same meat freshly coked. "Hence, palatability, a concept that is based around the sensory properties of the food, its taste, odour and texture, is an important factor in food selections for the domestic dog."

Romsos describes a study that was done to determine if dogs are able to regulate protein intake independently of energy intake, as it is known that dogs are able to regulate their intake of energy. It was found that by allowing dogs access to 2 diets that differed in protein and by rotating the position of each diet within the cage, the dogs were able to adjust their feeding pattern to maintain a constant protein intake without affecting energy intake. However, Romsos states that because the concentration of fat in the diet affects the self-selected protein, the fat to carbohydrate ratio was also varied in the 2 lower-protein diets. Romsos thus states that it is possible that a ratio of dietary fat to carbohydrate wider than that used in the study would effect protein intake in dogs.

The Wills referenced is directed to the general nutrient requirements of dogs and cats in which the composition of a balanced diet and factors affecting food intake are discussed.

Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), controls the consideration and determination of obviousness under 35 U.S.C. 103(a); KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1734-35, 167 L. Ed. 2d 705, 715 (U.S. 2007). The four factual inquires enunciated therein for determining obviousness are: (1) determining the scope and contents of the prior art; (2) ascertaining the differences between the prior art and the claims in issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) evaluating evidence of secondary considerations.

In this case, neither the level of ordinary skill in the art, nor secondary considerations are at issue. However, in order to assess the scope and content of the prior art properly, a thorough understanding of the invention must be acquired by studying Applicant's claims and the specification. M.P.E.P. § 2141. Thus, the inquiry begins with construction of Applicant's claims, explained below. Next, when ascertaining the differences between the prior art and the claims at issue, both the invention and the prior art references as a whole must be considered, and *all* claim limitations must be considered when determining patentability of Applicant's invention. M.P.E.P. §§ 2141; 2143. When this is properly done in this case, as shown below, it becomes clear that differences exist that preclude obviousness. And finally, the test for obviousness requires identification of a reasonable basis for combining the claimed elements in the claimed fashion. *KSR*, 127 S. Ct. at 1741; M.P.E.P. §2143. As shown below, this requirement is not met in this case, and no *prima facie* case for obviousness is made.

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Applying the proper test to this case begins with amended independent claim 1 directed to a method for determining the optimum macronutrient content of a diet for an individual companion animal. The method includes the steps of providing, over an extended and preselected period of time, different food compositions to the animal in which each composition provides an enriched source of fat, protein or carbohydrate, such that the animal can select and consume different and preferred quantities of each of the food compositions in order to achieve an optimum consumption of fat, protein and carbohydrate for the animal; then allowing the animal to consume the different and preferred quantities of fat, protein and carbohydrate from each of the compositions over the extended preselected period of time; and thereafter determining, from the consumed amount of fat, protein and carbohydrate from each of the compositions, a customized dietary regime that provides the optimum macronutrient content of a diet for the individual animal.

The Foreman reference does not teach a method for determining the optimum macronutrient content of a diet for an <u>individual</u> companion animal as described in amended claim 1. The Foreman references teaches feeding a pet a main course having a high protein and fat content, a side dish having a high carbohydrate content and a treat. The animal is not provided, nor is it allowed to select, over an extended and preselected period of time, different food compositions in which each composition provides an enriched source of fat,

protein or carbohydrate such that the animal can select and consume different and preferred quantities of each of the food compositions. According to Foreman, the assembler of the tray selects the food items in which the main course will always have a high protein and fat content and the side dish will always have a high carbohydrate content. In Foreman, the pet can only consume what is in the tray and is not able to consume different and preferred quantities of fat, protein and carbohydrate from each of the compositions over an extended preselected period of time, nor is it possible to determine, from the consumed amount of fat, protein and carbohydrate from each of the compositions, a customized dietary regime that provides the optimum macronutrient content of a diet for the <u>individual</u> animal.

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In Jewell, a single pet food having a high fat and low carbohydrate content is fed to the pet. As in Foreman, the pet is not able to consume different and preferred quantities of fat, protein and carbohydrate from each of the compositions over an extended preselected period of time, nor is it possible to determine, from the consumed amount of fat, protein and carbohydrate from each of the compositions, a customized dietary regime that provides the optimum macronutrient content of a diet for the individual animal.

In both the WO 01/97605 and WO 01/97630 references, the animal is fed one pet food product for the morning meal and the second pet food product is fed for the afternoon/evening meal. The morning meal has a higher protein content that the afternoon/evening meal and the afternoon/evening meal has a higher fat content that the morning meal. As in Foreman and Jewell above, the pet is given only one pet food product for each meal and is not able to consume different and preferred quantities of fat, protein and carbohydrate from each of the compositions over an extended preselected period of time, nor is it possible to determine, from the consumed amount of fat, protein and carbohydrate from each of the compositions, a customized dietary regime that provides the optimum macronutrient content of a diet for the individual animal.

The modification of the Foreman et al., Jewell et al., WO 01/97605 and WO 01/97630 references with Rice and Sepell does not cure the deficiencies of these references. Rice teaches free-choice feeding in which "a one-day supply of premium dry dog food" is made accessible to the dog and Serpell describes palatability preferences of dogs. Providing a pet free access to the tray of Foreman, the single pet food of Jewell, and the morning and

afternoon/evening meals of WO 01/97605 and WO 01/97630 will not allow the animal to consume the different and preferred quantities of fat, protein and carbohydrate from each of the compositions over the extended preselected period of time; and thereafter determining, from the consumed amount of fat, protein and carbohydrate from each of the compositions, a customized dietary regime that provides the optimum macronutrient content of a diet for the Nor will modifying the primary references with the palatability individual animal. preferences of Serpell result in the recited elements of amended independent claim 1.

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In the Rosmos et al. study, the dogs were able to adjust their feeding pattern to maintain a constant protein intake without affecting energy intake only when the fat to carbohydrate ratio was also varied. Romsos stated that because the concentration of fat in the diet affects the self-selected protein, it is possible that a ratio of dietary fat to carbohydrate wider than that used in the study would effect protein intake in dogs. Thus, it cannot be reasonably expected that if the food containing the carbohydrate, fat and protein contents as shown by the primary references were to be offered in a free-choice feeding method, that the dogs could be able to self-regulate even protein according to Rosmos, in addition to selfregulating carbohydrate and fat.

Willis teaches feeding practices for adult pets. In the section discussing the feeding regimen for dogs, Wills states that dogs have a good enough appetite to eat all they require in one meal per day and that it is satisfactory to adopt a once-a-day feeding regimen. The discussion goes on to state: "The correct number of meals for any adult dog is that which the owner and dog find most convenient. It is desirable to establish a routine and stick to it. Meal times are the high spot of most days and dogs quickly become accustomed to being fed at the same time and place each day." Regarding the feeding regimen for cats, Wills states that: "Cats do seek variety in their diet, as long as the new food is not too different from the familiar one, or the palatability too low. Repeated exposure to fresh supplies of a new food which is not initially acceptable to the cat may encourage to cat to overcome its reticence. Furthermore, cats often detect and may reject diets that are deficient in certain nutrients, so it is important that any diet offered is nutritionally complete." The fact that dogs become accustomed to routine and cats are picky eaters, has no relationship to providing, over an extended and preselected period of time, different food compositions to the animal in which each composition provides an enriched source of fat, protein or carbohydrate, such that the 9

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animal can select and consume different and preferred quantities of each of the food compositions in order to achieve an optimum consumption of fat, protein and carbohydrate for said animal. The modification of the Foreman et al., Jewell et al., WO 01/97605 and WO 01/97630 references with Willis does not does not cure the deficiencies of these references. In the Willis reference, an owner is supplying the pet with one pet food product per meal, which does not allow the animal to consume the different and preferred quantities of fat, protein and carbohydrate from each of the compositions over the extended preselected period of time; and thereafter determining, from the consumed amount of fat, protein and carbohydrate from each of the compositions, a customized dietary regime that provides the optimum macronutrient content of a diet for the individual animal. In order to make a proper prima facie case for obviousness, all claim limitations must be accounted for. M.P.E.P. § 2143.03. Therefore, this rejection fails to consider all elements of the claims and their meaning.

If an independent claim is non-obvious under 35 U.S.C. 103, than any claim depending therefrom is by definition non-obvious. Applicant respectfully submits that claims 3-8 depend at least in part from independent amended claim 1. Claims 2, and 9-10 have been cancelled. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claims 1-10 under 35 USC 103(a) as having subject matter unpatentable over U.S. Pub. No. 2001/0048955 to Forman et al. taken with U.S. Pat. No. 6,410,063 to Jewell et al., WO 10/97605 and WO 01/97630 in view of Rice ("The Dog Handbook", pages 48-49), Romsos et al. (JAVMA vol. 182(1), pp 41-43 1983) and further in view of Serpell ("The Domestic Dog", pages 104-106, 1995) and Wills, Josephine ("Adult Maintenance", BSAVA Manual of Companion Animal Nutrition & Feeding, Chap. 3, pages 44-46, 1996).

CONCLUSION

In view of the above, applicant believes the pending application is in condition for allowance.

The fee for a one month extension of time is being submitted with this response. If additional fees are due, please charge our Deposit Account No. 06-2375, under Order No. HO-P03189US0 from which the undersigned is authorized to draw.

Application No. 10/540,095 Amendment dated February 17, 2009 Reply to Office Action of November 7, 2008

Dated: February 17, 2009

Respectfully submitted,

Electronic signature: /Jan K. Simpson/

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Jan K. Simpson

Registration No.: 33,283

FULBRIGHT & JAWORSKI L.L.P.

Fulbright Tower

1301 McKinney, Suite 5100 Houston, Texas 77010-3095

(713) 651-5151

(713) 651-5246 (Fax)

Attorney for Applicant